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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,228	10/12/2001	Lothar W. Kleiner	ARC 2427 N1	9517

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ALZA CORPORATION
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EXAMINER

SCHLIENTZ, NATHAN W

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/976,228

Applicant(s)

KLEINER ET AL.

Examiner

Nathan W. Schlientz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20,28-32,35,48,50-52,55,57,58,60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20,28-32,35,48,50-52,55,57,58,60 and 61 is/are rejected.
- 7) ☐ Claim(s) 34,48,57 and 58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Nathan Schlientz can be reached at 571-272-9924.

Acknowledgement of Receipt

The Amendments and Remarks, filed 8 September 2006, have been received and fully considered.

Status of Claims

As a result of the aforementioned Amendments, Claims 1-16, 21-27, 34, 36-47, 49, 53, 54, 56, 59 and 62-64 have been cancelled, and Claims 17, 35, 48, 55, 57, 58, 60 and 61 have been amended. Claims 17-20, 28-32, 35, 48, 50-52, 55, 57, 58, 60 and 61 are pending and examined herein on the merits for patentability. No claim is allowed at this time.

Claim Objections

1. Claim 34 is objected to because of the following informalities: page 2 of the aforementioned amendments lists Claim 34 as cancelled, but page 4 states that Claim 34 is "(Previously Presented)". For the purposes of examination, Claim 34 is being treated as cancelled considering it is dependent from a cancelled claim, and the "Amendments to the Claims" lists it as canceled. The Applicant is required to put the

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appropriate status identifier "canceled". Examiner respectfully directs the Applicant's attention to MPEP 714 Rule 37 CFR 1.121. Appropriate correction is required.

2. Applicant is advised that should Claims 18 and 19 be found allowable, Claims 57 and 58 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 19 is dependent from Claim 18, which is dependent from Claim 17. Therefore, Claim 18 encompasses all the limitations of Claim 17, and further limits the predetermined temperature to about 45-80 °C, and Claim 19 encompasses all the limitations of Claims 17 and 18, while further limiting the period of time at elevated temperature to about 1-75 hours. Claim 57 has the same limitations as Claim 17, except that the predetermined temperature is about 45-80 °C, as in Claim 18; and Claim 58 has the same limitations as Claim 18, except the period of time at elevated temperature is about 1-75 hours, as in Claim 19. Therefore, Claims 57 and 58 have the exact same claim limitations as Claims 18 and 19, respectively.

Claim Rejections - 35 USC § 102

1. The rejection of Claims 1, 11-14, 36-38, 40-45, 53, 56 and 64 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,024,842 (hereinafter Edgren et al.) is hereby withdrawn in view of the aforementioned Amendments canceling the instant claims.
2. The rejection of Claims 1, 3, 10-16, 34, 36-45, 47, 53, 56, 59 and 64 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,728,396 (hereinafter Peery et al.) is hereby withdrawn in view of the aforementioned Amendments canceling the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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1. Claims 17-20, 28-32, 35, 48, 50-52, 55, 57, 58, 60 and 61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Peery et al. in view of Edgren et al.

Applicant claims:

The Applicant claims a method for processing rate controlling membranes comprising: a) providing a membrane made of polyurethanes or polyether blocked amides copolymers, b) holding at room temperature for 0.5 to 7 days, c) heating to from 30 to 5 °C below the melting temperature of the membrane, d) maintaining the heating for 1 to 250 hours, and e) incorporating in an implantable drug delivery device. In particular, the temperature is about 45 to 80 °C, and is held at this temperature for 1 to 75 hours. Also, Claims 32 and 52 require the membrane be positioned in sealing relationship with an internal surface containing an imbibing device and a piston dividing the drug and imbibing device, wherein the membrane accommodates the imbibing device. Claims 35, 55, 60 and 61 are drawn to the annealed rate controlling membrane.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Peery et al. teach the implantable drug delivery device (Figure 2) that is the same as the instant invention (Figure 4 of the instant specification). The device of Peery et al. further comprises a membrane made up of either a polyurethane or polyether blocked amides copolymers (column 6, lines 43-61; and Claims 10 and 17).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Peery et al. do not teach the process of annealing the membranes by heating to a predetermined temperature for a set amount of time, followed by cooling and incorporation into the implantable device. However, Edgren et al. teach an implantable (column 5, lines 6-8) device that is first coated with a subcoat followed by an overcoat (column 5, lines 16-18). The implantable device, as shown in Figure 6, comprises an inner compartment **24** comprising on one end an imbibing composition **26**, and on the other end a beneficial drug **25**; wherein, the compartment is coated with a semipermeable subcoat **22** with an opening, i.e. exit passageway **23**, on the same side as the drug. Therefore, the device of Edgren et al. is similar to that of Peery et al. in that the semipermeable subcoating allows external fluid to pass to the inner compartment, where the imbibing composition swells and the beneficial drug is then released through the exit passageway at a controlled rate. Thus, the semipermeable subcoating of Edgren et al. would need to be similar to the semipermeable membrane **26** of Peery et al., as shown in Figure 2, which allows external fluid to enter into the device thereby swelling an imbibing composition **20** and releasing a drug **18** through an exit passageway **36**.

Edgren et al. further teach the process of forming the subcoating and overcoating layers of the implantable device by annealing, wherein the coating forming composition is brought up to a preselected temperature (i.e. an annealing temperature), kept at the annealing temperature for a preselected amount of time, and finally cooling to room

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temperature (column 8, lines 3-11). Edgren et al. further teach that the annealing process results in an annealed subcoat that is permeable to the passage of fluid and maintains its physical and chemical integrity in a fluid environment of use (column 8, lines 28-31). Also, Edgren et al. teach the annealing temperature is about 20 to 75 °C, and the predetermined time for annealing is about 5 to 90 hours (column 8, lines 17-20).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to anneal the membranes of Peery et al. by heating to a predetermined temperature of about 20 to 75 °C for 5 to 90, cooling to room temperature, and then incorporating into the implantable device, as taught by Edgren et al. for the purpose of maintaining its physical and chemical integrity in a fluid environment of use.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments with respect to Claims 17-20, 28-32, 35, 48, 50-52, 55, 57, 58, 60 and 61 have been considered but are moot in view of the new grounds of rejection.


Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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